JUN 2 6 2002

K012690

# Adven Medical, Inc

*1001 Slaton Hwy.*
*Lubbock, Texas 79404*
*Tel: (806) 745-7718*
*Fax: (806) 745-0223*

## 510(k) SUMMARY

| | |
|---|---|
| Reference: | Adven Medical, Incorporated<br>Section 510(k) Notification<br>AMI Reprocessed Multiple Clip Appliers (Non Re-loadable) |
| Classification name: | LSR Disposable Stapler<br>Manual Surgical Instrument |
| Common/Usual Name: | Disposable Surgical Instruments |
| Proprietary Name: | AMI Reprocessed Multiple Clip Appliers |
| Establishment Reg. No.: | 1649663 |
| Classification: | The FDA has classified Manual, General Surgical Instruments as Class I devices under the General and Plastic Surgery Panel (21 CFR 878.4800)<br>As an implantable clip, Class II. |

AMI intends to market Reprocessed Disposable, Multiple Clip Appliers with non changeable reloads. Reprocessing Multiple Clip Appliers is performed by AMI to AMI Potocol Number 40017.

"Reprocessed," means all operations performed to render a contaminated single-use device patient ready (*Enforcement Priorities for Single-Use Devices Reprocessed by Third Party Reprocessors and Hospitals*). AMI is a "third party reprocessor" and reprocesses used single-used medical devices.

Appliers are sold new by the original manufacturers to the hospital. The hospital uses the appliers, collects them and ships them to AMI for reprocessing. Appliers are reprocessed by AMI as described in our reprocessing protocol Control Document Number 40017, and returns them to the hospital to be reused as a single-use device again.

AMI believes that single-use Appliers can be considered "reusable" - by AMI" as defined in the Food and Drug Administration Compliance Policy Guide #7124.16: they are able to withstand the necessary cleaning and sterilization process, the physical characteristics or quality of the device will not be adversely effected, and the device remains safe and effective for its intended use.

Adven Medical, Inc., Reprocessed appliers are substantially equivalent to Ethicon disposable surgical and endoscopic Ligaclip Multiple Clip Appliers currently marketed new by Ethicon under 510(k) 830503.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 6 2002

Adven Medical
Mr. Mark W. Aldana
President
1001 Slaton Highway
Lubbock, Texas 79404

Re: K012690
Trade Name: AMI Reprocessed Multiple Clip Appliers (non-reloadable)
Regulation Number: 878.4300
Regulation Name: Implantable Clip
Regulatory Class: II
Product Code: FZP
Dated: May 7, 2002
Received: May 9, 2002

Dear Mr. Aldana:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510)k) Number: K012690

Device Name: AMI Reprocessed Multiple Clip Appliers

Indications For Use:

Multiple clip appliers are indicated for ligation of tubular structures.

AMI intends to reprocess multiple clip appliers one time.

Reprocessed multiple clip appliers are single use devices.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012690

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___
(Optional Format 1-2-96)